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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/19/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/848,225

Applicant(s)

SHIROYAMA ET AL.

Examiner

Robert M. Joyner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of applicants' Amendment and Response filed on September 8, 2003.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the transitional phrase "consisting essentially of", yet Claim 5 attempts to include another active ingredient which would materially change the nature of the composition. Therefore, it is unclear if applicant intends for the composition to be closed or open upon examination of the instant claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (US 5294444) in combination with Kaneko et al. (WO 98/27958). Nakamura teaches a transparent cosmetic composition comprising a ceramide, a nonionic surfactant, an ionic surfactant and an aqueous medium (Col. 5, Claim 1). The nonionic surfactant polyoxyethylene hydrogenated castor oil (Col. 3, lines 1-23). The ionic surfactant can be anionic (Col. 3, lines 27-42). The aqueous medium is water (Col. 4, lines 12-16). Nakamura does not teach the specific ceramides of the instant claims.

Kaneko teaches a protective agent for skin and hair comprising a specific ceramide, a surface-active agent, a higher fatty acid and a lipid (Page 20, Claims 1-8). The high fatty acids are oleic acid or isostearic acid (Page 7, lines 5-26). The lipid is cholesterol (Page 7, lines 5-26). The specific ceramides recited in the prior art appear to have the same structure as the ceramides recited in the instant claims.

Neither Nakamura nor Kaneko expressly teach the exact concentration ranges recited in the instant claims.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amounts of the ingredients and to substitute one ceramide for another similar ceramide. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization. The primary reference clearly recites that a ceramide can be incorporated into the skin

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composition. The secondary reference teaches the specific ceramides and recites that they are suitable for skin and hair compositions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to the ceramides of Kaneko in the compositions of Nakamura for its art intended purpose. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the various types of hosts to receive the composition. One would be motivated to choose one ceramide over another to achieve similar expected results based on availability of each particular ceramide.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed September 8, 2003 have been fully considered but they are not persuasive. Applicants argue that the instant claims are drawn to a composition that consisting essentially of the ceramide, a long chain fatty acid, nonionic surfactants and water and that the prior art teaches the inclusion of ionic surfactants. Applicants argue that the ionic surfactants are skin irritants and are not desired in the instant invention. Further, applicants argue that the primary reference does not teach a true ceramide and no motivation exists to combine the references.

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Upon close examination of the specification and the instant claims (Claims 5 and 6), it appears that additional ingredients, including active ingredients (for example cholesterol or polyhydric alcohol), can be added to the composition other than the four main components of the ceramide, the long chain fatty acid, the nonionic surfactant and water recited in Claim 1 with the consisting essentially of language. Therefore, it is the position of the Examiner that the instant claims do not exclude the inclusion of ionic surfactants.

Further, the primary reference (Nakamura) includes in its list of active ingredients ceramides (See Claim 1). It is the position of the Examiner that substituting one skin care ceramide for another in cosmetic composition is within the skill of the art. One would be motivated to substitute one ceramide for another to achieve the same results of providing skin benefits to the user and to deliver those beneficial agents in a suitable and safe composition.

Therefore, the obviousness rejections are maintained.

### ***Conclusion***

Due to the new grounds for rejection, this action is deemed Non-Final.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes  
Patent Examiner  
Art Unit 1615  
November 12, 2003

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**